

FINAL

Environmental Impact Statement

Integrated Research Facility



Rocky Mountain Laboratories

Hamilton, Montana

April 2004



National Institutes of Health



U.S. Department of Health and Human Services

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**FINAL
ENVIRONMENTAL IMPACT STATEMENT
RML INTEGRATED RESEARCH FACILITY**

National Institutes of Health

Ravalli County

Hamilton, Montana

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Abstract

The National Institutes of Health (NIH) is considering constructing and operating an Integrated Research Facility at Rocky Mountain Laboratories (RML) in Hamilton, Montana. The Integrated Research Facility would include Biosafety Level - 4 (BSL-4) laboratories, in addition to BSL-3 and BSL-2 laboratories, animal rooms, offices, conference rooms, and break areas. The facility is needed to improve the nation's ability to study and combat emerging and re-emerging infectious disease and to protect public health in keeping with NIH's mission.

Two alternatives were considered in detail in the Final Environmental Impact Statement: the Proposed Action (build and operate the Integrated Research Facility), and No Action (continue current RML operations). Four additional alternatives were considered, but were eliminated from detailed study.

The agency's preferred alternative is the Proposed Action. The public comment period on the Final Environmental Impact Statement will close 30 days after the Notice of Availability appears in the Federal Register. Comments should be sent to Valerie Nottingham at the above address.

SUMMARY

INTRODUCTION

Rocky Mountain Laboratories' (RML) mission is to play a leading role in the nation's effort to develop diagnostics, vaccines, and therapeutics to combat emerging and re-emerging infectious diseases. Following events of September 11, 2001, and the anthrax attacks soon after, the public is aware of the potential for exposure of the civilian population to bioterrorism. President Bush and Congress directed the National Institute of Allergy and Infectious Diseases (NIAID) to increase its research into development of safe and effective measures to protect the public. These goals are commensurate with past and current research by NIAID. Research is needed to develop safe vaccines and drugs to prevent or cure infectious diseases. In response to this need for research directed at protecting public health, Congress authorized \$66.5 million to NIAID for construction of a biosafety laboratory and related infrastructure (Public Law 107-117, January 10, 2002). NIAID has also developed a Strategic Plan for Biodefense Research and a research agenda for priority (Category A) biological agents, which is included as **Appendix A** (USDHHS 2000a, b).

A lack of available and adequate facilities is a major impediment to the study of organisms. As a result, many important pathogens have received little attention recently and many have not been examined using the tools of modern science. This research deficit becomes most apparent now when there has never been a greater demand for information on the pathogens and host responses to them. Information from basic research studies is critical for development of effective vaccines and therapies to combat infectious diseases. Such products can be developed only through understanding the basic biology of disease-causing agents. Cutting-edge discoveries in infectious disease research have resulted from NIAID programs and it is proposed to enhance the capability of the Institute to carry out basic research on important pathogens in this proposed facility. These enhanced capabilities, once in place, would have an additional benefit to the American

public in that they would strengthen the Nation's ability to respond to outbreaks of naturally occurring diseases. Recent outbreaks of SARS and West Nile Fever underscore the need to have an extensive and flexible infrastructure to support infectious disease research to meet the challenge of emerging diseases.

NIAID has a history of research that has had global impacts on public health improvement. This research capability allows NIAID to address unknown, future health threats associated with emerging and re-emerging infectious disease. NIAID is comprised of both intramural and extramural research areas. The Division of Intramural Research (DIR) and the Vaccine Research Center (VRC) conduct intramural research. The DIR is located in laboratories on the main NIH campus in Bethesda, Maryland, the Twinbrook facilities in Rockville, Maryland, and at the Rocky Mountain Laboratories in Hamilton, Montana. DIR conducts research in virology, biochemistry, parasitology, epidemiology, mycology, molecular biology, immunology, immunopathology, and immunogenetics, and supports clinical, patient-centered research in allergy, immunology, and infectious diseases at NIH's Clinical Center (NIAID 2002a). NIAID supports extramural research, done by non-federal scientists in universities, medical schools, hospitals, and research institutions.

NIAID is one of 27 Institutes or Centers of NIH. NIH is one of 12 agencies of the U.S. Department of Health and Human Services.

As part of the expanded research program, NIH is proposing to construct an Integrated Research Facility and complete infrastructure upgrades to existing facilities at the RML campus in Hamilton. In the U.S., facilities to conduct research with pathogenic material at the highest level of containment are limited to Atlanta, Georgia; Frederick and Bethesda, Maryland; and San Antonio and Galveston, Texas.

PURPOSE OF AND NEED FOR ACTION

The purpose for the Proposed Action is to provide a highly contained and secure intramural laboratory at RML dedicated to studying the basic biology of agents of emerging and re-emerging diseases, some of which have potential as bioterrorism agents. Because of its traditional strengths in the area of infectious disease research and the federal funding parameters associated with NIAID's intramural laboratory program, the Integrated Research Facility is proposed to be located at RML in Hamilton, Montana.

In order to conduct necessary research to gain an understanding of pathogen and host response, specialized high-containment laboratories are required. The need for the Project (construction of the proposed Integrated Research Facility at RML) is based on the following aspects of the current facility at RML:

- RML is renowned for expertise in research on infectious microbes;
- Researchers at RML provide a core of unparalleled scientific knowledge uniquely qualified to develop strategies and products to counter emerging and re-emerging diseases;
- RML currently has BSL-2 and BSL-3 laboratories;
- Existing infrastructure at RML can efficiently and effectively provide a realistic, orderly, and comprehensive effort to safeguard the health of the American people through basic research as well as detection, investigation, control, and prevention of diseases.

Emergence of new diseases (e.g., HIV/AIDS, hantavirus pulmonary syndrome, West Nile fever, severe acute respiratory syndrome (SARS)) and re-emergence of drug-resistant pathogens (e.g., tuberculosis, malaria, *Staphylococci aureus*) are reminders that infectious diseases remain dominant features of national and international public health (USDHHS 1998; Fauci 2001). Societal, technological, and environmental factors (e.g., population growth, poverty, ease of travel, alteration of habitats) facilitate occurrence and spread of disease. A critical need exists for

continued research, not only on new diseases, but also on old and familiar ones.

SUMMARY OF PROPOSED ACTION

NIH proposes to construct an Integrated Research Facility to house Biosafety Level (BSL)-2, BSL-3, and BSL-4 laboratories, animal research facilities, administrative support offices, conference rooms, and break areas at the RML Facility in Hamilton, Montana. The Proposed Action would encompass approximately 105,000 square feet of building constructed within the existing 33-acre RML campus in the southwest portion of Hamilton.

The Integrated Research Facility and research programs would require additions and upgrades to the existing RML campus. Upgrades would include:

- A new chilled water plant and emergency power backup system;
- A new addition to Boiler Building 26 to house a new natural gas-fired boiler; and
- Construction of below grade systems and utility distribution tunnels to service the Integrated Research Facility.

Research at the RML site would include pathogenesis, immune response, vaccine, diagnostics and therapeutics work and will focus on RML's strength in vector-borne pathogen research. RML does not and will not conduct research to develop offensive biological weapons.

Biosafety Level 4 (BSL-4)

A BSL-4 laboratory would be constructed within the Integrated Research Facility to provide the highest possible level of protection for scientists and the public and to expand the research capability of RML. The use of a BSL-4 laboratory would be required for research of certain agents and experiments, such as testing of vaccines for emerging and re-emerging infectious microbial agents that are normally ranked at BSL-3 level. Stringent safeguards, including engineering and design features (see Appendix E) are required for BSL-3 and BSL-4 laboratory facilities to prevent pathogens from escaping into the environment. In addition, the BSL-4 laboratory would be designed

to prevent contact between pathogens and people inside the workspace and provide secure storage for infectious agents.

The BSL-4 laboratory would be located within the central core of the building, surrounded by a buffer corridor between the laboratory and the exterior. A specific facility operations manual would be prepared and adopted prior to operation of the laboratory.

PROJECT ALTERNATIVES

Alternatives were identified during the public scoping process or by RML during review and analysis of the Proposed Action. The following alternatives were considered technically infeasible, provided no environmental advantage over the Proposed Action or No Action, or did not meet the purpose and need:

- Build the Integrated Research Facility in Bethesda, Maryland
- Relocate Rocky Mountain Laboratories to a Less Populated Area
- Construct the Integrated Research Facility at Alternate Location
- Construct and administer the Integrated Research Facility by another agency, or at another NIH Location

The only alternative to the Proposed Action discussed in detail in this EIS is the No Action Alternative. Under the No Action Alternative, the Proposed Action would not be implemented at RML. Existing operations at RML would be maintained and operated at current levels.

SUMMARY OF IMPACTS

Analysis of potential impacts and mitigation measures associated with the Proposed Action and Alternatives is presented in Chapter 4 – *Environmental Consequences*. The following is a summary of potential impacts resulting from the Proposed Action and No Action Alternative.

SOCIAL RESOURCES

Proposed Action

Additional employment associated with the proposed Integrated Research Facility includes up to 200 workers at the peak of construction and about 100 employees in late 2005/early 2006 when the facility would be opened. Based on the Ravalli County rate of 2.45 persons per household, this would add a total of 245 new residents to the county. This represents between 1.4 percent and 3 percent of all new residents projected for the County, based on estimates in the Ravalli County Economic Needs Assessment (Swanson, 2002). Addition of new homes would result in increased business for homebuilders and real estate developers. School capacity is adequate for new growth, but operating and maintenance costs would increase to accommodate the new students. No impact is expected on the ethnic or gender make-up of the population.

Traffic around the RML associated with construction, delivery of equipment and materials would increase over the 2-year construction period. Following construction, traffic levels would likely remain elevated due to the 100 new permanent employees at RML (approximately 20 percent during peak hours), although large truck traffic to support RML would return to current levels.

No Action Alternative

Under the No Action Alternative, population growth and housing starts would likely continue at the current pace. Current levels of community services, programs, and infrastructure would not change. Current levels of traffic would continue in the neighborhood adjoining RML. Research on agents at the BSL-2 and BSL-3 level would continue.

COMMUNITY RISK

Proposed Action

Redundancy of safety equipment and procedures, operational safeguards, and monitoring systems inherent to biosafety laboratories reduce the risk

of an accidental release. Theoretically, human error or multiple, simultaneous mechanical failures could lead to accidental release of biological materials from a biosafety laboratory. The overall safety record of biomedical and microbiological laboratories also indicates that there is not a risk of accidental release. Nevertheless, in order to address community safety concerns, the NIH applied both qualitative and quantitative risk assessment strategies to investigate potential community impacts of the proposed Integrated Research Facility at the RML. The qualitative assessment included a literature review regarding laboratory acquired infections; a review of all infectious disease research protocols performed by the NIAID requiring BSL-2 with BSL-3 practices, BSL-3, or BSL-4 facilities for the past two decades; review of all NIAID accidents associated with these laboratories; injuries and illnesses during the same period of time; review of RML medical waste incinerator operations, infectious waste handling procedures, animal containment, and procedures for biological material shipment. Additionally, a survey was conducted to determine the safety records of BSL-4 laboratories worldwide with 20 or more years of operating experience. Additionally, the NIH performed a quantitative assessment of risk with regard to infectious agent release to the surrounding Hamilton community from the proposed BSL-4 Integrated Research Facility at RML. The quantitative risk assessment was driven by reasonably foreseeable, credible threat scenarios and addressed spills and work disruption; safety system operation and potential failures; and fire and explosion. The modeling tool used to perform these analyses is the Maximum Possible Risk (MPR) model developed by the NIH. Anthrax, in spore form, was chosen as the worst-case scenario agent based on public health impact and dissemination potential (Rotz *et. al.* 2002).

Qualitative and quantitative risk analysis revealed that the potential risk to the community surrounding the Rocky Mountain Laboratories and specifically the IRF from potential release of infectious agents is negligible.

No Action Alternative

Under the no action alternative, human error or multiple, simultaneous mechanical failures could

lead to accidental release of biological materials from the existing RML facilities. However, safety equipment and procedures, operational safeguards, and monitoring systems inherent to biosafety labs significantly reduce the risk of accidental release. The overall safety record of biomedical and microbiological laboratories indicates that there is not a significant risk of accidental release. Therefore, the potential risk to the community surrounding the Rocky Mountain Laboratories from the existing laboratories in which infectious disease research is currently conducted is negligible.

ECONOMIC RESOURCES

Proposed Action

The Proposed Action would have direct economic impacts on both the City of Hamilton and Ravalli County throughout construction and operation. Payroll associated with construction of the Integrated Research Facility is estimated at \$4.7 million. Using the current economic multiplier in the 2002 Ravalli County Needs Assessment, approximately \$18.9 million in economic activity would be gained in the 2-year construction period.

Annual payroll for 100 new employees is estimated at \$6.6 million. Added to the current \$10.4 million annual payroll, RML would contribute \$17 million annually to the local economy. The RML and the proposed Integrated Research Facility meet community goals listed in the 2002 Ravalli County Economic Needs Assessment, Ravalli County Growth Policy, and the City of Hamilton Comprehensive Master Plan.

Public finance revenues would increase from income tax on the Integrated Research Facility-related construction and operations payrolls, as well as income of spouses and older children of the additional RML employees, increased number of licensed vehicles, and property tax revenues based on additional new homes and property assessments.

No Action

Selection of the No Action alternative would not have direct economic impacts. An opportunity to

stabilize the local economy with government jobs and increased tax revenue would be lost, slowing the realization of economic development goals of the city and county.

NOISE

Proposed Action

Additional noise producing equipment would be associated with construction of the Integrated Research Facility. With specified noise reduction measures, the Integrated Research Facility would meet RML's 2003 noise guidelines. Reasonably foreseeable action and recently implemented noise reduction features have and would reduce noise further.

No Action

There would be no change in the noise level from not implementing the Proposed Action. Periodic noise measurements will be taken by an independent professional acoustic contractor to evaluate compliance with the voluntary guidelines. In the event that noise levels exceed the guidelines, funding will be sought to institute remedial measures. Reasonably foreseeable action and recently implemented noise reduction features have and would reduce noise further.

VISUAL QUALITY

Proposed Action

The primary visual impact of the Proposed Action would be the addition of a large building into an area of existing buildings. Existing and proposed stacks associated with the Boiler Plant would create vertical linear contrast to surrounding structures. Ventilation stacks on the Integrated Research Facility would not be visible from off the campus. Proposed landscaping around the Integrated Research Facility would have a positive impact on visual quality in the neighborhood.

No Action

There would be no change in existing visual condition under the No Action Alternative. The site is vegetated with scrub grasses and weeds.

There are also dirt/gravel roadways and areas of deteriorating asphalt. A variety of outside clutter and covered storage is visible but could be removed to improve facility aesthetics.

HISTORICAL RESOURCES

Proposed Action

The Proposed Action would be partially visible from the RML Historic District. The Integrated Research Facility could affect the view from the historic district, but there would be no adverse effect on the qualities inherent in the Historic District.

No Action

Selection of the No Action Alternative would have no effect on the existing historic district.

AIR QUALITY

Proposed Action

Gaseous and particulate air contaminant emissions would be generated during normal laboratory operations. Source emissions would comply with all air quality standards. Use of the incinerator to dispose of refuse generated at the facility, including those from the Integrated Research Facility, would increase from 2-3 days/week to 3-4 days/week. Permit limits (Montana Air Quality Permit 2991-04) on the incinerator would not be exceeded.

No Action

Emissions from RML would remain at current levels under the No Action Alternative.

WATER SUPPLY AND WASTEWATER

Proposed Action

The estimated increase in water use of 17,000 gallons per day represents about a 1 percent increase in the amount of water pumped by the City of Hamilton Department of Public Works (CHDPW) on a daily basis. With respect to available capacity, the Integrated Research Facility

would use about 5.3 percent (12 gpm of 226 gpm) of system capacity. Increased demand for water created by operation of the Integrated Research Facility would have a minor impact on the CHDPW municipal water supply system, and the system would be able to handle the increased demand.

Approximately 1,000 to 1,200 pounds of solids per day are currently handled at the CHDPW. (Lowry 2003). The Integrated Research Facility would generate an estimated 28 pounds of additional solids, representing a 2.3 to 2.8 percent increase in solids load to the CHDPW wastewater facility.

The Proposed Action would not have an impact on the solids handling capacity at the CHDPW because the planned upgrade of the solids handling capacity at the facility would accommodate current and future needs of Hamilton as well as additional solids produced by the Integrated Research Facility.

No Action

Selection of the No Action Alternative would have no adverse affects on the Hamilton water supply and wastewater treatment systems.

CUMULATIVE EFFECTS

Cumulative effects on the environment resulting from past, present and reasonably foreseeable actions (NIH, other organizations, growth), along with construction of the Integrated Research Facility would include an increase in area traffic, increased demand on community services and programs, increased water use and demand on CHDPW water and sewage treatment systems, and population growth in the Bitterroot Valley. Increased payroll would benefit the local economy and tax revenue from income and property assessments would benefit local and state government. These effects may be compounded by the expansion of Corixa, Inc. and growth projected in Hamilton.

PREFERRED ALTERNATIVE

The NIH has identified the Proposed Action as the preferred alternative.